

**REMARKS**

Claims 1-39 are pending in the application. Claims 9-11 and 16-39 are withdrawn from consideration. Claims 1 and 15 have been amended. Upon entry of these amendments, claims 1-8, and 12-15 will be pending and under active consideration. Claim 1 is independent.

Applicant notes that Claims 9-11 and 16-39 remain withdrawn from consideration without prejudice to pursuing the withdrawn subject matter in this or other continuation or divisional applications.

Applicant submits respectfully that the amendments presented herein are supported fully by the claims and/or specification as originally filed and, thus, do not represent new subject matter.

In particular, Claim 1 has been amended to now recite that the method comprises treating a subject suffering from a herpes virus infection or a disease associated with a herpes virus infection comprising: administering to the subject a therapeutically effective amount of a substance exhibiting mammalian alpha-1-antitrypsin (AAT) or AAT-like activity in combination with a therapeutically effective amount of an antiviral nucleoside derivative comprising vidarabine, azidothymidine, ganciclovir or a combination thereof.

Claim 15 has been amended so as to correct the inadvertent punctuation errors. In particular, Applicant has amended Claim 15 so as to delete all of the originally provided species and provide each species with its correct punctuation and also provide each species with a roman numeral identifier.

The amendment to the claims is supported fully by the claims and/or specification as originally filed and, thus, does not represent new subject matter. In particular, the amendment to Claim 1 finds support at page 26, lines 11-14.

Applicant respectfully requests entry of the amendments and remarks made herein into the file history of the present invention. Reconsideration and withdrawal of the rejections set forth in the above-identified Office Action are respectfully requested.

**I. Formal Matters**

**A) Claim Objection**

At page 2 of the Office Action, the Examiner indicates that claim 15 is objected to because of the punctuation errors in the claim, the correction of which Applicant inadvertently did not provide the required notations. The Examiner also indicates that new text has been entered in claim 15 without indication. Applicant wishes to advise the Examiner that the new text was entered inadvertently. Applicant has amended claim 15 so as to correct all of the inadvertent punctuation errors and to remove the inadvertent recitation present in lines 25-26. In particular, Applicant has amended claim 15 so as to now delete all of the originally listed species. Each species has now been identified with its correct punctuation and each species has also provided with its own roman numeral identifier.

**II. The Rejection Under 35 U.S.C. § 103(a) Should Be Withdrawn**

**A. The Rejection Over Lezdey (U.S. Patent No. 5,532,215) and Gosselin et al. (U.S. 5,627,185)**

The Office Action, at page 5, rejects Claims 1, 2, 5- 8, and 11-14 as allegedly being obvious over Lezdey (US 5,532,215) and Gosselin *et al.* (U.S. 5,627,185) under 35 U.S.C. § 103(a) for the reasons of record. The Office Action alleges that Lezdey teaches a method to treat a subject suffering from a herpes virus infection, eczema or related conditions with an AAT compound by topical or systemic dosing at about 1 mg/kg body weight (column 5, lines 16- 33, column 6, line 32 - column 7, Example 1, column 12, lines 10- 12, Claims 1 and 2). The Office Action further alleges that Lezdey teaches that AAT is a serine proteinase inhibitors that is in the subgroup called serpins (column 3, lines 39-41) and that alpha 1- protease inhibitor (alpha 1- PI) is another name for AAT (column 5, line 19). The Office Action alleges that Gosselin et al. teach that acyclovir is known to have anti-Herpes activity (column 1, lines 39- 42). Applicant traverses respectfully.

Without acquiescing in the propriety of arguments presented by the Office Action, Applicant has amended Claim 1 to no longer recite the antiviral nucleoside derivative acyclovir. Applicant respectfully submits that Lezdey, taken either alone or in combination with Gosselin,

does not teach or suggest the combination of using a substance exhibiting mammalian alpha-1-antitrypsin (AAT) or AAT-like activity with a therapeutically effective amount of an antiviral nucleoside derivative comprising vidarabine, azidothymidine, ganciclovir or a combination thereof to treat a subject suffering from a herpes virus infection or a disease associated with a herpes virus infection. Accordingly, the Lezdey reference, taken either alone or in combination with Gosselin reference, fails to meet the threshold required for establishing a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

Accordingly, Applicant submits respectfully that the rejection of 1, 2, 5- 8, and 11-14 under 35 U.S.C. § 103(a) have been overcome, and Applicants request respectfully that the rejection of 1, 2, 5- 8, and 11-14 under 35 U.S.C. § 103(a) be withdrawn.

**B. The Rejection Over Gyorkos (U.S. Patent No. 5,618,792) and Gosselin et al. (U.S. Patent No. 5,627,185)**

The Office Action, at pages 5-6, rejects Claims 1, 3, and 4 as allegedly being unpatentable over Gyorkos (US 5,618,792) and Gosselin et al. (U.S. 5,627,185). The Office Action alleges that Gyorkos teaches AAT related compounds can be used to treat conditions that are caused by an imbalance in the level of alpha 1- PI including invasion of malignant tumors and related conditions (column 1, lines 28- 35). The Office Action alleges that while Gyorkos does not name all the conditions as per the claims, one of skill in the art would allegedly realize the range of conditions that can be treated by the method of Gyorkos. The Office Action further alleges that Gosselin et al. teach that acyclovir is known to have anti-Herpes activity (column 1, lines 39-42). Applicant respectfully traverses the rejection.

Without acquiescing in the propriety of arguments presented by the Office Action, Applicant has amended Claim 1 to no longer recite the antiviral nucleoside derivative acyclovir. Applicant respectfully submits that Gyorkos, either alone or in combination with Gosselin, does not teach or suggest the combination of using a substance exhibiting mammalian alpha-1-antitrypsin (AAT) or AAT-like activity with a therapeutically effective amount of an antiviral nucleoside derivative comprising vidarabine, azidothymidine, ganciclovir or a combination thereof to treat a subject suffering from a herpes virus infection or a disease associated with a herpes virus infection. Accordingly, neither Lezdey alone nor the combination of Gyorkos with

Gosselin meets the threshold required for establishing a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

Accordingly, Applicant submits respectfully that the rejection of Claims 1, 3, and 4 under 35 U.S.C. § 103(a) has been overcome, and Applicant requests respectfully that the rejection of Claims 1, 3, and 4 under 35 U.S.C. § 103(a) be withdrawn.

**C. The Rejection Over Lezdey in view of Gyorkos (U.S. Patent No. 5,618,792) and Gosselin et al. (U.S. Patent No. 5,627,185)**

The Office Action, at pages 6-7, rejects Claims 1 and 15 as allegedly being unpatentable over Lezdey in view of Gyorkos (US 5,618,792) and Gosselin et al. (U.S. 5,627,185). The Office Action cites Lezdey, Gyorkos and Gosselin *et al.* for the prior reasons of record. The Office Action alleges that one of ordinary skill in the art at the time of the invention would have allegedly known that the compounds described by Gyorkos had the activity exhibited by mammalian alpha-1-antitrypsin that are required to meet the requirements of the method of Lezdey. The Office Action further alleges that one of ordinary skill in the art at the time of the invention would have allegedly known the benefits of the compounds taught by Gyorkos as discussed above and would have used them in the method of Lezdey. Finally, the Office Action alleges that one of ordinary skill in the art at the time of invention would have combined the treatments of Lezdey in view of Gyorkos and Gosselin et al. with the expectation of at least additive effect of the two treatments. Applicant respectfully traverses the rejection.

Without acquiescing in the propriety of arguments presented by the Office Action, Applicant has amended Claim 1 to now no longer recite the antiviral nucleoside derivative acyclovir. Applicant respectfully submits that Lezdey, taken either alone or in combination with Gyorkos and Gosselin, does not teach or suggest the combination of using a substance exhibiting mammalian alpha-1-antitrypsin (AAT) or AAT-like activity with a therapeutically effective amount of an antiviral nucleoside derivative comprising vidarabine, azidothymidine, ganciclovir or a combination thereof to treat a subject suffering from a herpes virus infection or a disease associated with a herpes virus infection. Accordingly, neither Lezdey alone, nor the combination

of Lezdey with Gyorkos and Gosselin, meets the threshold required for establishing a prima facie case of obviousness under 35 U.S.C. § 103(a).

Accordingly, Applicant submits respectfully that the rejection of Claims 1 and 15 under 35 U.S.C. § 103(a) has been overcome, and Applicant requests respectfully that the rejection of Claims 1 and 15 under 35 U.S.C. § 103(a) be withdrawn.

### **CONCLUSION**

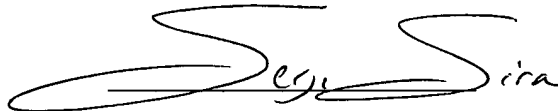
Applicant submits that the application is in condition for allowance. Favorable reconsideration, withdrawal of the rejections set forth in the above-noted Office Action, and an early Notice of Allowance are requested.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

### **AUTHORIZATION**

Applicant believes there is no fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account No. 50-1710 or credit any overpayment to same.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Serge Sira", with a large, stylized "S" at the beginning.

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